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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,096	12/27/2005	Akira Yagi	2520-0131PUS1	8923
2292	7590	05/02/2007		
BIRCH STEWART KOLASCH & BIRCH			EXAMINER	
PO BOX 747			E BRAHIM, NABILA G	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			05/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailto:[mailroom@bskb.com](mailto:mailroom@bskb.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/512,096	YAGI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Nabila G. Ebrahim	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/15/2004, 10/21/2004.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

The receipt of Information Disclosure Statements dated 11/15/2004 and 10/21/2004 is acknowledged.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 5, and 6 provide for the use of 3'-Hydroxymethyl-4-hydroxypyrrolido [1,2-f] 2', 5'-piperazinedione, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 5, and 6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 102***

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yagi et al. EP1067138 (hereinafter Yagi).

Yagi teaches hydroxyproline derivative such as the structure of Compound 2 disclosed which is 3'-Hydroxymethyl-4-hydroxypyrrolido [1,2-f] 2', 5'-piperazinedione, (see formula 3-1). The composition can be topically administered in the form of powders, granules, and ointments, and being administered orally or non-orally [0022]. Note that the recitation of instant claim 2 “the preparation is a remedy for atopic dermatitis” is the intent of use, which has no weight in determining patentability.

3. Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yagi et al. WO994754 (hereinafter Yagi).

**The EP1067138 version will be used as a translation.**

Yagi teaches the use of hydroxyproline derivative such as 3'-Hydroxymethyl-4-hydroxypyrrolido [1,2-f] 2', 5'-piperazinedione for the treatment of liver damage and discloses that the efficacy which is expected for the compounds of the invention is illustrated as follows:

- (1) Decrease in activities of cytosolic enzymes (GOT, GPT, gamma -GTP, ALP, LAP and LDH, etc.) in a damaged liver.
- (2) Increase in the hepatic uptake of bilirubin.

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(3) Hepatoprotection (prevention and suppression of degeneration and necrosis of hepatocytes).

(4) Suppression of hepatofibrosis and hyperplasia of hepatic fibrous tissue, and absorption of hyperplastic hepatic fibrous tissue and interstitial connective tissues.

(5) Anti-hepatolipocytosis (decrease in lipid precipitation to a liver and improvement of lipid degeneration in hepatocytes).

(6) Activation of tissue respiration (Activation of succinic acid dehydrogenase and stimulation of tissue respiration in a liver, and activation of metabolism in hepatocytes)

(7) Stabilization of hepatocyte membrane.

4. The relation between liver problems and the allergies such as atopic dermatitis and rhinitis is known in the art as evidenced by the documents cited in the office action (Iwasaki et al. and Kimata H.)

Accordingly, it is inherent that these compounds would be effective in treating allergies including rhinitis, and atopic dermatitis as recited in the instant claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yagi et al. EP1067138 (hereinafter Yagi) in view of Iwasaki et al. Study of liver function in babies with atopic dermatitis by using 13-C-methacetin breath test, Arerugi, 1992 Jun;41(6):645-53 (hereinafter Iwasaki) and further in view of Kimata H. Fatty Liver in Atopic dermatitis, Allergy. 2001 May;56(5):460 (hereinafter Kimata).

Yagi has been discussed above.

Yagi does not teach explicitly the treatment of allergies by the compound disclosed.

Iwasaki teaches the relation between liver damage and atopic dermatitis. The reference discloses that level of serum Got levels in babies with atopic dermatitis and food allergies.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the compound disclosed by Yagi in the form of topical administration to treat atopic dermatitis because Iwasaki teaches the relation between the liver serum GOT elevation (disclosed by Yagi to be corrected by the compound disclosed) and atopic dermatitis.

Iwasaki does not teach relation between liver damage and other types of allergy.

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Kimata teaches the relation between fatty liver and other types of allergy such as allergic rhinitis and also atopic dermatitis. Kimata teaches that in cases of fatty liver (type of liver damage as disclosed by Yagi) there are tendency in the patients to have atopic dermatitis, and allergic rhinitis (see table 1).

It would have been obvious one of ordinary skill in the art at the time the invention was made to use the compound disclosed by Yagi in the form of topical administration to treat allergic rhinitis and atopic dermatitis because Kimata teaches that it has been reported that liver dysfunction is sometimes found in children with these types of allergies. Accordingly, it would have been obvious that treating liver problems taught by Yagi would improve allergies. The expected results would be a topical administration of a composition comprising 3'-Hydroxymethyl-4-hydroxypyrrolido [1,2-f] 2', 5'-piperazinedione to treat allergies such as atopic dermatitis and allergic rhinitis.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

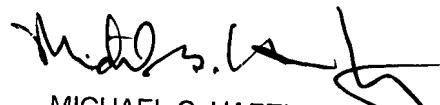
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim, M.D.

4/13/07



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER